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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,943	11/14/2003	Easton L. Manderson	3023-005	7421

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ALFRED A. STADNICKI  
ANTONELLI, TERRY, STOUT & KRAUS, LLP  
SUITE 1800  
1300 NORTH SEVENTEENTH STREET  
ARLINGTON, VA 22209

EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

THA

<b>Office Action Summary</b>	<b>Application No.</b> 10/706,943	<b>Applicant(s)</b> MANDERSON, EASTON L.	
	<b>Examiner</b> James L. Swiger	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 12 is objected to because of the following informalities: Line 2 of Claim 12 reads "nearthe." Examiner suggests adding a space –near the— to prevent claim ambiguity. The claim was understood per examiner's recommendations. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-6,7-8,16-18 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. Claims 4,5,8,16 and 18 claim part of the human body, namely part of a fractured bone. Claim 7 is drawn to the naked eye of the surgeon. And claims 6 and 17 are dependent upon their respective claims listed above that contain non-statutory subject matter. Thus claims 4-6,7-8,16-18 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

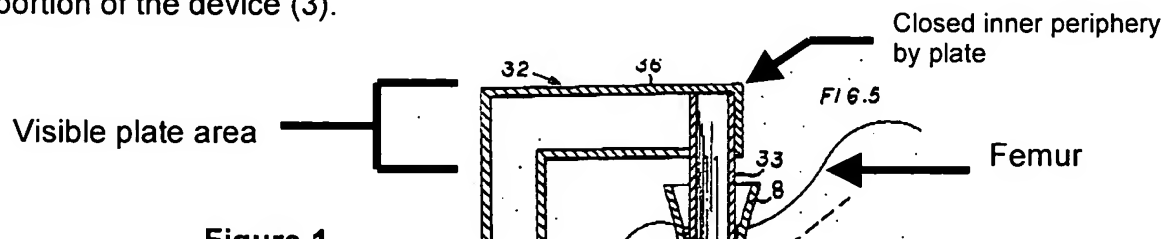
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant case, the specification and drawings do not disclose enough information regarding the end plate to make an accurate assessment of the claims.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Marino (U.S. Patent No. 4,733,654). Marino discloses a device having an intramedullary nail (see Fig. 1a below), having a first end and second end, a curved longitudinal axis, an end plate disposed at the first end (see Fig. 1 below), and a distal portion of the device (3).



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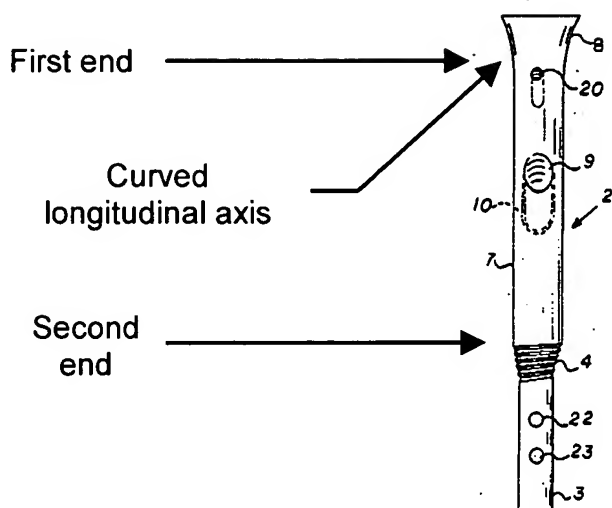


Figure 1a.

The above device also has a smaller diameter at the second end, and smaller diameter at the distal shaft area (3).

Marino also discloses an aperture formed by an inner periphery (See Fig. 2 below)

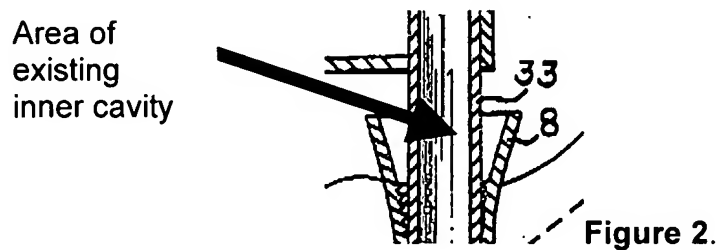


Figure 2.

closed by the end plate (see Fig. 1 above). Marino further discloses a device having a first screw hole and a corresponding second screw hole in the cylindrically shaped tubular body. (See Fig. 3 below.)

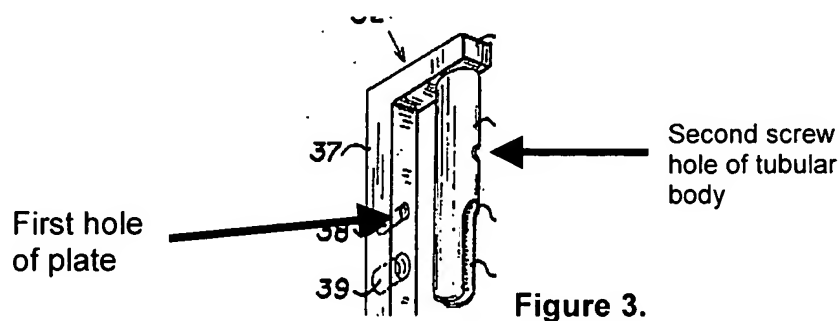


Figure 3.

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Marino also discloses that the intended bone is for use on a femur (Col. 2, line 33), and has a hollow core with threads (4), and is capable of insertion without a jig. The end plate can also be viewed by the surgeon in the device of Marino (see Fig. 1 above).

The above invention also includes a locking screw with threads that can be secured into the bone cavity (26 and 27, and Col. 3, lines 3-5).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino in view of Comte et al (U.S. Patent No. 4,875,475). Marino describes the claimed device except for a proximal portion of the nail that can be separated from the tubular shaft portion. Comte et al. shows a teaching of an upper portion that is capable of functioning as a nail, that can be separated from the proximal portion. (See top of Fig. 1.) It would have been obvious to one skilled in the art at the time the invention was made to incorporate the teaching of Comte et al. into the device of Marino to allow greater flexibility in the adjusting of the intramedullary implant (Col. 5, lines 1-32).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino in view of Warburton (U.S. Patent No. 6,527,775). Marino discloses the claimed device except for a curved proximal portion in one plane that intersects with the second plane formed by the rest of the implant. Warburton teaches a rod (26) that has a curved upper

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portion that would create a second plane in addition to the other axis of the device (a). It would have been obvious to one skilled in the art at the time the invention was made to incorporate the curved axis of Warburton with the device of Marino to enable a better fit within the medullary canal (Col. 5, lines 55-65).

Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino in view of Warburton '775. Marino discloses the stated device except for an angular arrangement of the tubular body and a distal diameter of no less than 7 mm. Warburton discloses a range of about 10-90 degrees (Col. 13, lines 33-36), covering the ranges of 20-25, and 5 -7 degrees states by the applicant. Warburton also discloses a distal diameter of 2-8mm, again meeting the applicant's claim. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Marino with the claimed ranges of the applicant. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Conclusion***


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see PTO-892 for further references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 11/15/2005  
JLS

  
EDUARDO C. ROBERT  
PRIMARY EXAMINER